Background

The malaria blood stage vaccine candidate SE-36 is based on the serine repeat antigen of *Plasmodium falciparum*. Epidemiological studies have shown that antibodies against SE36 correlates with lower parasitemia in Solomon Island residents. In a phase Ib trial conducted in Uganda, the BK-SE36 vaccine, SE36 formulated with aluminium hydroxide gel, was found safe and immunogenic. Interestingly, highest level of IgG anti-SE36 protein associated with protection against severe malaria were found in the youngest Ugandan trial participants.

Objectives

To assess the safety and immunogenicity of the BK-SE36 vaccine in a randomised controlled double blind age deescalating phase Ib clinical trial in younger (≤ 5 years) malaria exposed children living in Burkina Faso.

Methods

Healthy participants (108) were included in two age cohorts, one consisting of 54 children aged 25-60 months and the other of 54 children aged 12-24 months. Trial participants received 3 intramuscular or subcutaneous injections of the BK-SE36 vaccine at Day0, Week 4 and 26. Participants allocated to the control group received the control Synflorix® vaccine via intramuscular route at Day 0 and Week 26 and saline at Week 4. The participants were followed during one year. Immune responses were evaluated by ELISA, ELISpot and parasite carriage by microscopy and PCR.

Results

Preliminary data from an interim analysis data collected one month after the last immunisation indicated that the vaccine was safe, well tolerated and induced an IgG anti-SE36 response in these younger populations. The trial latest safety, immunogenicity and preliminary efficacy results will be presented.